PCORI Funding Announcements: Cycle I Awardees

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PCORI Funding Announcement (PFA) Cycle I awards were approved by PCORI's Board of Governors on December 18, 2012. All awards, including proposed amounts and project periods, were approved by PCORI's Board pending a business and programmatic review by PCORI staff and completion of a formal award contract. More information on each awarded project, including final award amounts, are posted on PCORI's website (pcori.org).

PCORI Funding Announcements: Cycle I Awardees

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Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication and Dissemination

Addressing Disparities

II. List of Awardees by State

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Assessment of Prevention, Diagnosis, and Treatment Options

Georgia

David W. Loring, PhD
EMORY UNIVERSITY
Cognitive AED Outcomes in Pediatric Localization Related Epilepsy (COPE)

Epilepsy is the most common serious chronic neurological disease in childhood, and localization related epilepsy (LRE) is the largest pediatric epilepsy group in aggregate. Treatment of children with epilepsy involves medications designed to stop their seizures, although all epilepsy medications may have adverse side effects on cognition that can reduce attention, processing speed, and memory. The risk of detrimental long-term medication effects on cognitive abilities is a major concern for parents. Although the medications used to treat pediatric LRE do not differ in their ability to control seizures, they likely have different effects on cognition. However, there have been no studies of possible differential treatment effects on cognition in pediatric LRE, and medications are selected based on non-scientific biases of the treating physician without full understanding of potential treatment effects on cognition.

Children with LRE represent a particularly vulnerable population for treatment related cognitive side effects because they are still developing cognitively and socially. Negative treatment effects on cognition can diminish developmental outcomes. If medication differences in the amount of cognitive side effect risk exist, then selecting treatments associated with poorer cognitive outcome needlessly interferes with cognitive development and school performance. Choosing a medication with the least cognitive impairment will maximally preserve cognitive abilities, which not only has implications for school achievement, but also for longer term outcomes, including subsequent employment and vocational options.

This study will determine changes in cognitive abilities (eg, attention) associated with three of the most common medications used to treat pediatric LRE. Children who are newly diagnosed with LRE by their treating physicians and are between 6 and 12 years of age will be randomized to levetiracetam, lamotrigine, or oxcarbazepine. There will be 12 study sites throughout the United States. Children will be studied using well-validated tests of cognition before taking medications and again following three and six months of treatment when they visit their physician for routine medical care. Because the doctors

and families will know what drug is being used, attention will be studied using a computerized test, and other performance measures will be obtained by a blinded assessor. If attentional differences between drugs are seen, then anti-epilepsy medications can be selected with the least detrimental cognitive effects. If no differences are seen, treatments can be selected based on other factors, such as cost. Regardless of the specific findings, results of this study will provide the information needed to help parents and their clinicians choose treatment options that maximize cognitive abilities in children with LRE and provide the data needed for practice guidelines to be established on the basis of cognitive side effect risks.

Massachusetts

Laurel K. Leslie, MD, MPH
TUFTS MEDICAL CENTER
Comparative Effectiveness of Adolescent Lipid Screening and Treatment Strategies

PCORI's mission is to help people make informed healthcare decisions through research that is guided by patients, caregivers, and the broader healthcare community. The goal of this application, submitted by Co–Principal Investigators Laurel K. Leslie, MD, MPH, and Sarah de Ferranti, MD, MPH, is to improve decision making regarding lipid (ie, cholesterol) screening and treatment in adolescents. Specifically, we ask the following research question: An adolescent and his/her parent are asked by a primary care provider about their interest in a lab test for lipid screening. What is the comparative effectiveness (ie, risks and benefits) of different lipid screening and treatment strategies, taking into account that adolescent's sociodemographic and clinical characteristics and his/her personal and parental preferences?

Whether all adolescents should be screened and treated for high lipid levels is controversial. A National Heart Lung and Blood Institute (NHLBI)–funded expert panel published guidelines in November 2011 recommending universal lipid screening of children ages 9 to 11 and 17 to 21 years and consideration of treatment with statin medications when lipid levels exceed certain levels and do not respond to lifestyle (ie, nutrition and exercise) counseling. Previous guidelines published by the American Academy of Pediatrics and the U.S. Preventive Services Task Force have concluded there is insufficient evidence regarding the risks and benefits of universal screening and statin use in children and adolescents to recommend universal screening. Which approach is best is unclear. Most screening and treatment decisions influence a variety of outcomes, such as what health problems a patient may develop as a result of a disorder or its treatment and when they might occur, how long a patient might expect to live, and how satisfied a patient is with his or her current health. Very little is known about how adolescents and parents perceive lipid screening and treatment choices or what outcomes they prefer, and no adolescents or parents were included on the NHLBI expert panel.

This study is designed to engage adolescents and parents, as well as other stakeholders, to answer two of PCORI's four patient-centered questions within the context of this current controversy. Specifically, we seek to answer the questions: "What are my options and what are the potential benefits and harms

of those options?" and "What can I do to improve the outcomes that are most important to me?" We will work with adolescents and parents to address our aims:

1. Characterize adolescent and parent preferences with regard to lipid screening and treatment

2. Examine the comparative effectiveness of different screening and treatment strategies

A panel of adolescents and parents and a panel of researchers, clinicians, and policy makers will guide us throughout the course of the study and ensure its relevance to patients, their caregivers, and other stakeholders.

Michigan

Francesca Tentori, MD, MS

ARBOR RESEARCH COLLABORATIVE FOR HEALTH

Selection of Peritoneal Dialysis or Hemodialysis for Kidney Failure: Gaining Meaningful Information for Patients and Caregivers

Every year, more than 100,000 patients start dialysis to treat kidney failure in the United States. Two types of dialysis are available: hemodialysis (HD) and peritoneal dialysis (PD). HD is done with a machine in a dialysis clinic. PD can be done at home, if the patient or family is willing to perform his or her dialysis treatments. In general, patients survive as long on HD as they do on PD. Based on specific clinical parameters and a patient's needs, one of the two dialysis types is usually going to be a better fit for a given patient. For example, older patients may not want to be responsible for performing their own treatment, and HD may be a better fit for them. On the other hand, PD may be a better choice for patients who want to be able to travel. The challenge for patients with kidney failure is to identify the dialysis type that best fits their lifestyle. However, there is very little information regarding factors that are important to patients starting dialysis, and often patients choose a dialysis type without fully understanding how it will impact their lives. Patients and their families need more information to be able to make better decisions. PD use is much lower in the United States than in other countries, perhaps reflecting the fact that many patients are not given appropriate information regarding this type of dialysis. Given recent financial pressure on kidney doctors to treat more patients with PD, it is even more important that patients receive better information when making a decision regarding dialysis type.

The goal of this study is to identify factors that matter the most to patients with kidney disease and study how they are impacted by different types of dialysis.

To understand what is most important to them, we will interview more than 130 patients with kidney disease, some before and some after they start dialysis. We will compare factors reported as important across different types of patients; for example, among men and women, or among those who work outside of the house and those who do not. Using the infrastructure of an existing study of more than 6,800 dialysis patients, we will compare factors identified during the interviews between patients treated with HD and PD. Based on these results, we will develop a Web site presenting information on

kidney disease and questions on personal preferences, which will help patients understand which dialysis type is better for them.

Results from our study will provide practical information regarding the choice of dialysis type to patients with kidney disease and their families. Patients who are better informed will be able to identify and choose the best dialysis type for their lifestyle and needs. Providing scientific evidence to help patients in their decision process is of great importance, especially at such a stressful time in their lives.

Minnesota

Erik Paul Hess, MD, MS
MAYO CLINIC
Shared Decision Making in the Emergency Department: The Chest Pain Choice Trial

Background: Chest pain is the second most common reason patients visit emergency departments (EDs) across the United States. To avoid missing a heart attack diagnosis, doctors frequently admit very low risk patients to the hospital when it is not necessary. This results in unnecessary patient worry and anxiety, untimely disruption in patients' lives, unnecessary testing, and increased healthcare costs.

We first developed a Web-based tool to reliably determine the future risk of a heart attack. Then, incorporating feedback from patients, doctors, and researchers, developed a patient education tool—Chest Pain Choice—to help patients better understand the tests that are being performed to determine the cause of their chest pain, what these tests might show, their individualized 45-day risk of a heart attack, and the available management options.

In a study at the Mayo Clinic, researchers tested the impact of Chest Pain Choice by randomly selecting ED patients with chest pain to use the patient education tool with their clinician or to receive usual care. Compared to patients randomized to receive usual care, patients who used Chest Pain Choice were more knowledgeable about their care and their risk for a heart attack, were significantly more involved in the decision-making process, and chose to be admitted to the hospital less frequently without any adverse events.

Objectives: We want to improve care using the best science and taking into account patient values, preferences, and circumstances. In this study we plan to compare Chest Pain Choice to usual clinical care in four diverse hospitals. This will help patients and doctors know if Chest Pain Choice will work in their hospital.

Specific aim: We will test if Chest Pain Choice improves patient-centered outcomes and decreases health care utilization in four diverse hospital EDs.

Methods: Patients and other stakeholders have been and will continue to be involved throughout the research process. We will randomly select patients at low risk for a heart attack to receive Chest Pain Choice or usual care at four diverse hospitals.

Expected impact: If the effectiveness of Chest Pain Choice is demonstrated in several diverse hospital emergency departments, it will improve patient-centered care for millions and safely decrease health care utilization.

North Carolina

Christopher Ethan Cox, MD, MPH
DUKE UNIVERSITY
Improving Psychological Distress Among Critical Illness Survivors and Their Informal Caregivers

Why is this important? Nearly 800,000 Americans receive mechanical ventilation for acute respiratory failure in the intensive care unit (ICU) each year. Afterward, more than 60% of both patients and their family caregivers suffer from psychological distress, such as depression, anxiety, and post-traumatic stress disorder (PTSD) for longer than a year after discharge. Patients and families told us that they need help with their distress because it worsens their quality of life. More specifically, patients said that learning how to adapt (that is, how to cope) with the physical and emotional changes of critical illness would be helpful. In fact, most ICU survivors use coping skills infrequently, which worsens psychological distress. But patients also told us that they wanted more information about critical illness, recovery, and what to expect. A lack of information increases PTSD symptoms. However, there are few treatments for this distress that can overcome ICU survivors' physical disability, great distance from expert medical centers, and concerns about how much treatments would cost. Therefore, we developed two treatments to address coping and lack of information.

What is the main goal? We aim to compare which of two treatments provided by telephone—a coping skills training (CST) program or an education program about critical illness—are more effective in reducing psychological distress and improving quality of life. Also, we will determine if unique groups of people with special characteristics have especially good improvement—and, if so, what personal factors explain this response.

How will we know which treatment is better? We will determine which treatment is most helpful by comparing participants' levels of psychological distress and quality of life, using surveys over six months. We will also record patients' own descriptions of how the treatments impacted their daily lives. The study would take three years and would be performed at five medical centers across the United States that treat patients with diverse backgrounds and illnesses; 250 ICU survivor-family member pairs will be randomly assigned (eg, a coin flip) to receive either the CST program or the education program. Treatments consist of six weekly telephone calls with a trained staff member, Web-based modules, and handouts.

How will this help others in the future? This research is important because it aims to improve long-term recovery for entire families by focusing on a devastating, common, yet inadequately addressed problem. These treatments were developed with the direct input of patients and families. These treatments represent a new direction in treating critical illness, because they can be delivered inexpensively by phone, easily adapted to future technologies, overcome barriers to care common to ICU survivors, and shared easily by phone or computer with others in need across the world.

Janet Prvu Bettger, ScD
DUKE UNIVERSITY
Comparative Effectiveness of Rehabilitation Services for Survivors of an Acute Ischemic Stroke

Stroke is a sudden attack on the brain that often requires long-term chronic care. It is the leading cause of serious long-term disability among adults. Of the seven million adult stroke survivors, most need help at some level. Stroke survivors who need constant care three months after their stroke have a high risk of dying by 12 months. It is possible to reduce disability caused by a stroke. Rehabilitation care after being in the hospital for stroke is the prime healthcare service for reducing disability and learning to manage day to day. Yet, there are several options for this one service. The benefits and risks of the different options are not clear. About 60% of stroke survivors older than 65 years receive some rehabilitation. The most common inpatient services are provided in inpatient rehabilitation facilities (IRF) and skilled nursing facilities (SNF). For those who go home from the hospital, the most common services are home health (HH) and outpatient (OP) care, and 40% receive no rehabilitation. Which option will support the best outcomes given a person's unique needs is unknown. This lack of evidence leaves stroke survivors, family caregivers, and clinicians with little guidance to make an informed decision about the rehabilitation services to choose based on individual needs. To address this gap, we will conduct a series of novel comparative effectiveness studies. We propose to first identify factors that predict use of rehabilitation after being in the hospital for an acute ischemic stroke. We will then compare the effectiveness of high (IRF) versus low (SNF) intensity short-term inpatient rehabilitation.

Finally, we will compare the effectiveness of community-based options, including OP and HH versus no rehabilitation. These studies will use data linked from seven primary sources: the nation's largest clinical registry for acute stroke (the American Heart Association Get With The Guidelines—Stroke program) with key details about survivors' clinical status and care; longitudinal Medicare claims in five data files with relevant service use data; and a large stroke cohort study (AVAIL) offering downstream patient reported outcomes. Our stroke survivor and caregiver advocates suggest our primary study outcome be "living independently" (defined as survival without significant disability and not living in a nursing home). Secondary outcomes will be functional status, depression, change in work status, disease self-management, quality of life, readmission, long-term care placement, and survival. Our observational research methods include propensity score and instrumental variable analyses of this rich integrated data set. This research addresses a critical decision that occurs in acute stroke care about 800,000 times each year. Trade-offs between rehabilitation service types are unknown. New evidence-based knowledge from this research will help guide individual decisions and improve future practice, policy, and patient-centered outcomes.

Pennsylvania

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CHILDRENS HOSPITAL OF PHILADELPHIA
Comparative Effectiveness of Intravenous vs Oral Antibiotic Therapy for Serious Bacterial Infections

Some children get serious bacterial infections that require hospitalization and then a long course of antibiotics to completely treat the infection. Examples of these serious infections include ruptured appendicitis (when the appendix gets inflamed and bursts, releasing bacteria into the abdomen), complicated pneumonia (when an infected pocket of pus forms either in the lung or between the lung and chest wall), and osteomyelitis (an infection of the bone). To extend the duration of antibiotic therapy after discharge from the hospital, doctors will often insert a long catheter called a PICC line in the child's vein, which can stay in the body for several weeks. However, PICC lines require a fair amount of maintenance and training of caregivers in their use; require children to restrict their activities; and can lead to serious complications, such as blood stream infections and clots. An alternative to PICC lines is extending the duration of antibiotic therapy with oral antibiotics (pills or syrup) that achieve high levels of medicine in the blood and do not have the extra work, inconvenience, and risks of PICC lines. Unfortunately, there are very few high quality studies that have demonstrated that oral antibiotics are just as good as intravenous antibiotics delivered via a PICC line, and so many doctors still recommend the PICC line treatment option. Also, no studies have been done to compare the impact of these two treatment options on the quality of life of the children and their caregivers.

In this proposal, we outline a series of projects to compare oral antibiotics vs intravenous antibiotics delivered via a PICC line in children who require prolonged (at least one week) home antibiotic therapy after hospitalization for three different serious bacterial infections: ruptured appendicitis, complicated pneumonia, and osteomyelitis. To see whether oral antibiotics are just as good as PICC lines, we will use data collected from more than 15,000 children with one of these three infections who were hospitalized at one of 43 US children's hospitals during the years 2009 to 2011 and determine whether PICC lines resulted in fewer rehospitalizations for treatment failure than oral therapy. To see what impact the choice of treatment option has on patient and caregiver quality of life and ability to take the medicine, we will spend 18 months surveying at least 1,000 patients (and their caregivers) who are discharged from four large children's hospitals with either prolonged oral or intravenous therapy after hospitalization for treatment of ruptured appendicitis, complicated pneumonia, or osteomyelitis. In all our comparisons, we will use special statistics to make sure that we are comparing similar patients in the two treatment groups so that these are fair comparisons.

Michael J. Schneider, DC, PhD
UNIVERSITY OF PITTSBURGH
A Comparison of Non-Surgical Treatment Methods for Patients with Lumbar Spinal Stenosis

Background: Lumbar spinal stenosis—known by patients as "arthritis of the spine"—is a condition that is very common, found in about 30% of older adults. It is the most common reason for people older than 65 to have back surgery. These operations are expensive and risky, with a high number of complications

that cause many patients to be re-admitted to the hospital. A large number of patients with stenosis do not need back surgery and can be treated with other methods, such as physical therapy, chiropractic, exercise, and medication. But we just do not have enough good research to tell us which treatment works best for which patient and under which circumstances. This research study hopes to provide more information about the effectiveness of the various non-surgical choices for managing stenosis.

Objectives: This study will directly compare the effectiveness of three common non-surgical treatment approaches for stenosis:

1. Usual medical care that involves prescription drugs and/or injections (epidural) into the spine

2. Group exercise in supervised classes given in a community center setting

3. Hands-on (manual) therapy and rehabilitative exercises given in a clinic setting by physical therapists and chiropractors

The researchers are interested in answering several questions that are important to patients:

• How do group exercise and manual therapy with rehabilitative exercise compare with usual medical care?

• How does community-based group exercise compare with clinic-based manual therapy and rehabilitative exercise?

• Are group exercise classes an effective and safe alternative for older adults with stenosis?

• Are there any key findings from what the doctor finds on examination that would be helpful in determining which type of treatment would be best for individual patients?

Methods: This research study will involve 150 adults who are at least 60 years old and have been diagnosed with lumbar spinal stenosis. The research volunteers will be divided into three groups, each group receiving one of the three types of treatments listed above under Objectives. The determination of which type of treatment each person receives will be determined by chance, using a computerized version of flipping a coin. This is a process known as randomization, which scientists think reduces the bias in research studies. A series of tests and questionnaires will be given to the patients before and after they get treatment and comparisons will be made to see how much improvement they made with each of the types of treatments. Finally, the researchers will compare the differences between the three treatment groups to see if certain types of treatment produced better results than others and if there were any examination findings that could be used to predict which type of patient would do better with which type of treatment.

Washington

Dan Cherkin, PhD, MS
GROUP HEALTH COOPERATIVE
Evaluation of a Patient-Centered Risk Stratification Method for Improving Primary Care for Back Pain

Background: Many Americans suffer from back pain for which no specific cause has been identified. Doctors in the United States do not have a standard toolkit of helpful treatments for addressing non-specific back pain. This contributes to frustration and unrelieved suffering for many patients and a sense of helplessness for many doctors. Recently, researchers in England developed a tool called "STarT Back," which helps doctors identify the types of treatments that are most likely to help patients with different pain experiences. This tool divides persons with back pain into three categories based on their answers to nine simple questions about their pain and its effect on their lives. Doctors can then recommend treatments that are most likely to be helpful for patients in each category. This method has not yet been tested in the United States where health care is very different than in England. This project will test an enhanced version of the method at Group Health, a healthcare system in Washington State.

Objectives: A research team at Group Health will test how well an enhanced version of the STarT Back method works for its patients with back pain. Because this method is new in the United States, it is important to find out if it meets the needs of patients and doctors and whether it can be easily used in the doctor's office. The goals of this project are:

1. Adapt the STarT Back method for use at Group Health, using its computerized health record system.

2. See how well the method works in three Group Health clinics, compared with three similar clinics where the method is not in place. We will learn from patients and doctors whether the method improved the treatment process and provided patients with greater relief from their back pain.

3. Share the results of this study with other groups, including patients, doctors, healthcare leaders, and other scientists.

Methods: It is important to understand whether using the method helps provide patients with more pain relief and improves their quality of life. We will invite patients visiting their primary care doctors for back pain to take part in the study. We will also ask doctors and care teams from these clinics to be part of this research. Patients who agree to be in the study will be asked questions about their back pain soon after their doctor visit and again several months later. These questions will be asked in a telephone survey. This information will allow us to see if using the method in doctors' offices results in better pain relief and better quality of life. We will also ask a small number of patients more in-depth questions to find out if there are ways we can improve the method to make it easier for doctors to use with their patients. People with back pain will be part of the research team. They will give their opinions about all details of the study, including the use of the method, the questions we ask patients and doctors, and how we report the results of the study.

Improving Healthcare Systems

Massachusetts

Jeffrey L. Schnipper, MD, MPH
BRIGHAM AND WOMEN'S HOSPITAL
Relative Patient Benefits of a Hospital-PCMH Collaboration Within an ACO to Improve Care Transitions

When a patient is admitted to the hospital and then discharged home, there is important information that needs to be communicated and understood by: (a) patients, (b) caregivers (anyone who helps take care of patients, including family or friends), and (c) the outpatient team (the medical providers that care for patients after they are home, such as primary care providers). Recent health reform efforts are changing the way health care is provided in order to improve care and reduce costs. One of these changes is the development of Accountable Care Organizations—large medical organizations that take responsibility for lowering costs and improving care for a defined group of patients. Another change is the conversion of regular primary care practices into Patient-Centered Medical Homes, with more staff and better technology to improve patient-doctor communication and the management of chronic illnesses. In theory, Patient-Centered Medical Homes and hospitals within Accountable Care Organizations have a vested interest in improving the discharge process so that patients recover fully and do not have to return to the hospital. Our question is whether we can leverage this situation and redesign the discharge process so that there is better communication between the hospital medical team, patients, caregivers, and the outpatient medical team so that patients do as well as possible after they return home. This redesign will include nurses to help coordinate care, pharmacists to make sure medications are taken safely, a home visit by a visiting nurse, a follow-up appointment within three days of discharge, and healthcare “coaches” to motivate patients at home.

The goals of our study are:

1. To design and implement a set of procedures (“the intervention”) to improve patients’ experiences when they are discharged home from the hospital.

2. To look at how the intervention affects problems that are known to occur after discharge, including medication issues, worsening medical problems, or the need to come back to the hospital. We will study how well patients recover the ability to do the things they could do before they were admitted and their opinions of the discharge process.

3. To understand the best way to put the intervention into place at different hospitals and practices and which kinds of patients benefit most from it.

This study will involve about 1,800 patients admitted to two different hospitals from 50 primary care practices that are becoming Patient-Centered Medical Homes as a part of a new Accountable Care Organization.

The results of this study will help healthcare leaders decide whether and how to adopt these kinds of interventions. Patients and caregivers will have more information to help them decide whether to join or stay with these kinds of new medical practices.

Maryland

Gloria Reeves, MD

UNIVERSITY OF MARYLAND BALTIMORE

The Family VOICE Study (Value Of Information, Community Support, and Experience): A Randomized Trial of Family Navigator Services vs Usual Care for Young Children Treated with Antipsychotic Medication

Family-centered mental health treatment of children values and supports the role of parents in their child's recovery. However, medications are often the primary focus in community treatment. Young children, even preschool-age youth, are increasingly being treated with antipsychotic medication for serious mood and behavior problems. This medication may be necessary to address safety issues (such as severe aggression), but it can cause serious side effects, such as obesity. Also, medication-only treatment does not follow recommended care for these types of problems. Psychosocial treatments (for example, programs that coach and empower parents to manage their child's difficult behaviors) are highly recommended as part of comprehensive (medication and psychosocial) child treatment. Parent involvement in psychosocial treatment has clear benefits for their child's mental health and, unlike medication, the effects can last long after treatment is completed. However, problems related to access (for example, long waiting lists) and use (for example, parent mistrust of mental health services) of services are common.

Maryland, as with other states, has developed a system to improve medication safety by reviewing health information about the child to determine if the treatment is appropriate. This review reduces unnecessary medication treatment and makes sure that children have adequate health screening before starting any treatment. Children who are approved for medication treatment have moderate-to-severe mental health problems, which supports their need for comprehensive (medication and psychosocial) treatment, instead of medication-only treatment. In this study, we are partnering with parents/family advocates, child-serving agencies, and health providers to develop a Family Navigator Service to link with this medication program. Family Navigators are individuals who have cared for their own child with mental illness. The navigators will support parents, provide information on psychosocial treatment options, and address barriers to using services. The goals of this program are to improve use of psychosocial services and to improve parent empowerment, support, and satisfaction with their child's mental health treatment. We also expect that the Navigator Service will improve the child's overall mental health and reduce the likelihood that he/she will need a medication dose increase or another medication added over the initial treatment period. The Navigator Service will be provided for parents of public insured children who are 10 years old and have just been approved for antipsychotic medication treatment. The Navigator Services will be provided by phone, so this service can support families in both rural and urban settings. Our long-term goal is to develop a Family Navigator program that strongly supports family-centered treatment of children and can be used to help families in other underserved areas beyond Maryland.

New York

Helena Temkin-Greener, PhD
UNIVERSITY OF ROCHESTER
Improving Palliative and End-of-Life Care in Nursing Homes

One in three Americans dies in a nursing home or in a hospital, shortly following transfer from a long-term care facility. The proportion of deaths occurring in nursing homes is projected to increase to 40% by 2020. Excellence in palliative and end-of-life (EOL) care must become a priority for these long-term care institutions. However, findings from nursing homes point to high incidence of pain and poor management of other symptoms and excessive reliance on hospitalizations, indicating inadequate EOL care quality. Expert opinion and research have suggested that poor EOL quality in nursing homes may be due to lack of palliative care training among staff and absence of EOL care protocols or guidelines, but research demonstrating that attention to these factors improves outcomes is absent. While dedicated care teams have been shown to improve outcomes for nursing home residents in need of specialized care, the impact of palliative care teams in improving resident outcomes has remained largely unstudied and untested. This will be the first randomized controlled trial to evaluate the impact of palliative care teams on resident and staff outcomes, and care processes, in nursing homes.

The specific aims will address the following questions:

Aim 1: Is palliative care team intervention effective in improving nursing home residents' EOL outcomes, such as pain, shortness of breath, in-hospital deaths, hospitalizations, and presence of advance directives?

Aim 2: Is palliative care team intervention effective in improving nursing home staff EOL care processes and outcomes, such as assessment of symptoms, skills in delivering care, communication, teamwork, and satisfaction?

We will adapt existing palliative care guidelines for EOL care, endorsed by the National Quality Forum, to the nursing home environment, deploy the adapted practice guidelines through a palliative care team model, and evaluate the effectiveness of this intervention on resident EOL outcomes and staff care processes and outcomes. We will employ a randomized controlled trial design and a difference-in-difference analytic approach. Thirty nursing homes in upstate New York have been recruited for the study, in both urban and rural areas. Stakeholders will include residents; family members; staff; policy makers; and others at local, state, and national levels.

Oregon

Jennifer E. DeVoe, MD, Dphil
OREGON COMMUNITY HEALTH INFORMATION NETWORK
Innovative Methods for Parents and Clinics to Create Tools (IMPACCT) for Kids' Care

Background: Health insurance is important for children. Public insurance programs are available to many children, but some families report confusion about how to get and keep this insurance. Community health clinics can help families get and keep health insurance for their children.

Objectives: We will work with families, policy makers, and community healthcare providers to develop and test new computer tools to help people in the clinic find pediatric patients in need of insurance and communicate with their families about public insurance programs. These tools will be based on technologies currently used to help patients and clinics manage chronic diseases. We will test the tools by comparing two clinics using the tools and two clinics not using the tools. We will look to see if children in the clinics using the tools are more likely to have health insurance and also more likely to receive certain healthcare services, compared to children in the clinics without such tools.

Methods: First, we will ask families, healthcare providers, and policy makers about the best types of computer tools to support insurance outreach by community health clinics. We will also visit clinics to understand how they could best use these tools. We will build the tools based on this feedback. Second, we will ask some families and healthcare providers to try out the tools, to make sure they are easy to use and helpful in meeting their needs. When families and healthcare providers are satisfied with the tools, we will have two clinics begin using the tools. Next, we will look at information from electronic medical records and insurance records to see if children from these two clinics using the tools have higher rates of insurance coverage and of needed healthcare services after the tools are put into place. We will also compare the overall rates of insurance and healthcare services of the children in the two clinics that used the new tools with children in the two clinics that are not using the tools. We will also ask healthcare providers and families about how they use the tools, whether they like them, and if they think the tools work well to help families get and keep health insurance for their children.

Importance: If computer tools built in this study are proven to work well, they will help clinics and families improve health insurance coverage and health care for children. This study will take place in a large network of community health centers, so we will be able to quickly spread the tools to more than 500,000 families in our network. We will build the tools in a way that they can be used by many other clinics with computer capabilities.

Pennsylvania

James M. Schuster, MD, MBA
UPMC CENTER FOR HIGH-VALUE HEALTH CARE
Optimizing Behavioral Health Homes by Focusing on Outcomes That Matter Most for Adults with Serious Mental Illness

Background: Adults with serious mental illness (SMI) frequently have unmet medical needs that place them at risk for adverse health outcomes. While there are proven ways to manage and/or prevent serious medical conditions common among this population, information is needed to understand their impact on outcomes that matter most for patients, particularly in community mental health centers (CMHCs) where most adults with SMI receive their care and rural areas where locating and receiving healthcare services can be challenging.

Objectives: Building on the work of a group of stakeholders in rural Pennsylvania, the UPMC Center for High-Value Health Care and our patient, provider, and payer partners will test two promising ways for promoting the health, wellness, and recovery of adults with SMI. One way will help patients manage their health and health care through a Web-based portal and peer support and the other through interactions with nurses during clinic visits. We will address four questions that patients have identified as important to them:

1. Given my mental and physical conditions, what should I expect will happen to my overall health, wellness, and recovery when I engage in the new services offered by my CMHC?

2. If I choose to participate in these services, what are the potential advantages or disadvantages to me?

3. In what ways can I become more active in managing my own health and health care?

4. Which of the services that my CMHC could make available to me will impact outcomes that I care about and help me make the best decisions about my health and care?

We will compare the impact of these services on outcomes of interest to patients and explore how patient characteristics and level of involvement in services affect outcomes. By showing which services improve outcomes for whom under what circumstances, we will inform positive patient heath choices and key stakeholder decision making to support these choices, thereby advancing health system improvement efforts to avoid untimely death and disease in this population.

Methods: We will target 2,810 Medicaid-enrolled adults who have or are at risk for chronic medical conditions and receive care at rural CMHCs for participation. Eight CMHCs will be randomly assigned to one of the two services with an estimated 1,124 patients involved in each group of four clinics. We will collect information from patients, caregivers, and clinic staff at different points in time during the study. Patients will be asked to complete questionnaires, and additional data on their service use will be gathered. Some patients and providers will also be interviewed about their experiences with care. We will examine these data to learn if, how, and why the new services improve outcomes over time. This

information will help us understand patient and other stakeholder views about the services and, if appropriate, ensure their continued and/or expanded availability.

Washington

Clarissa Hsu, PhD

GROUP HEALTH COOPERATIVE

Creating a Clinic-Community Liaison Role in Primary Care: Engaging Patients and Community in Health Care Innovation

Background: Chronic conditions such as diabetes are becoming more and more common. By 2020, about 157 million Americans will likely have at least one chronic condition, and 81 million will have two or more. Chronic conditions cause seven in 10 deaths and two in 10 disabilities. Health care for chronic conditions tends to cost a lot and could do a much better job of meeting patients' needs.

Chronic conditions can be treated by specialists or by primary care teams. Patients with chronic diseases tend to get better care, at a lower cost, when a primary care team coordinates their care. These patients can stay even healthier when their care teams work with community organizations, such as the YMCA or local support groups, to meet their needs. There is a need to develop and rigorously evaluate interventions that build on the Expanded Chronic Care Model to create stronger partnerships between primary care and community resources, because currently such interventions and evidence of their efficacy is rare.

Goals of this study: We will work with patients to design a new role for a clinic-community liaison. The liaison will link healthcare clinics with community organizations—and help create lasting relationships between them. This strategy has the potential to increase patients' ability to get what they need from both their community and their health care. Our goals are to:

• Create new ways to involve patients in designing their own health care. We will develop processes and tools to help patients contribute ideas for how care should be designed.

• Design and test a new clinic-community liaison role for primary care teams. This will help patients access the healthcare and community resources they need to prevent and treat chronic conditions. We will see how the liaison affects the outcomes that patients care about most. These include patient experience and satisfaction, quality of care, quality of life, and efficient use of both patient and healthcare resources.

How we will conduct this study: We will use both qualitative and quantitative data. Using qualitative data means looking closely at what patients do and say. We get it by observing patients, interviewing them, and talking with them in focus groups. Quantitative data is information about doctor visits, lab tests, treatments, and other health information. In this study, it will include a patient experience survey and data from Group Health's computer systems. This study design lets us combine traditional clinical data with rich information that describes patient experience.

What we hope this study will achieve: We hope this study will improve care for chronic conditions by involving patients in designing their care. We also hope having a community-clinic liaison will give patients better options for managing or preventing chronic disease.

Communication and Dissemination Research

Florida

Tim Wysocki, PhD
NEMOURS CHILDREN'S CLINIC
Shared Medical Decision Making in Pediatric Diabetes

Treatment adherence in type 1 diabetes (T1D) tends to decline among adolescents, increasing risks of acute and chronic complications, excess health care use, poorer quality of life, and T1D-related family conflict. Poor adherence is associated with psychiatric and family dysfunction and often persists into early adulthood. Therapeutic advances such as continuous subcutaneous insulin infusion (CSII or insulin pump) and continuous glucose monitoring (CGM) could improve metabolic control and quality of life. But, teens often do not benefit fully from such advances. Many studies of adults show that patient-centered communication styles predict more favorable clinical outcomes. Shared medical decision making (SMDM) interventions have improved outcomes among adults with diabetes and other conditions. Research in pediatrics has also shown that patient-centered and family-centered communication styles predict favorable outcomes, but most of this research is in primary care and has not studied youth with chronic conditions. Because there have been no controlled trials of SMDM with chronically ill youths, we propose a randomized controlled trial of an SMDM intervention compared with usual clinical practice (UCP). Qualitative interviews of youths and parents who have previously faced these decisions and reliance on expert consultants, pediatric endocrinologists, and diabetes educators will precede the trial and provide valued input for refining the planned intervention and adapting the structured SMDM format for pediatrics. Then, 120 youths aged 11 to 17 years with T1D who are candidates for CSII or CGM (and a parent/caregiver) will be recruited and randomized at four sites. The SMDM intervention will be delivered via iPad, facilitated by a certified diabetes educator (CDE) in a standardized, yet individually tailored format. SMDM will employ multimedia decision aids prepared with the award-winning Nemours Center for Children's Health Media in accordance with pertinent international standards for delivery via iPad. SMDM will also include individualized assistance from the CDE in assuring that each youth's and parent's preferences, values, and cultural beliefs are carefully addressed. After a baseline evaluation and randomization to SMDM or UCP, effects on the primary outcome (treatment adherence; device utilization) and secondary outcomes (glycemic control, treatment alliance, decision conflict and regret, treatment satisfaction, diabetes-related distress, and self-efficacy) will be measured over one year. Mixed effects modeling will be the primary analytical technique for evaluating effects on primary/secondary outcomes, examining selected variables as

moderators and mediators of treatment effects, and assessing whether such effects are comparable for the three medical decisions of interest. The results will verify whether SMDM in this context enhances treatment adherence, device use, and parent/patient-reported outcomes in youth with T1D.

Iowa

Ryan Michael Carnahan, PharmD, MS
UNIVERSITY OF IOWA
Extension Connection: Advancing Dementia Care for Rural and Hispanic Populations

The need to balance serious side effects with effectiveness of antipsychotics for behavioral and psychological symptoms in Alzheimer disease and other dementias sets the stage for difficult decisions for patients, families, and healthcare providers. While evidence supports the effectiveness of certain atypical antipsychotics in treating behavioral disturbances, these drugs have been found to increase the risk of death and stroke in people with dementia. Despite these warnings, antipsychotic use in people with dementia remains common, and, in many cases, it does not meet criteria for appropriate use. Training providers to understand proper evaluation strategies, non-drug management, and antipsychotic selection and use may improve antipsychotic utilization patterns and, as a result, the safety and quality of life of people with dementia. Through a project currently funded by the Agency for Healthcare Research and Quality, we have developed a toolkit and online training program to improve management of problem behaviors and reduce inappropriate antipsychotic use in dementia. However, we have identified unmet needs. This collaboration of the Iowa Geriatric Education Center, the Health Effectiveness Research Center, Iowa State University Extension and Outreach, and the Texas Consortium Geriatric Education Center proposes to test a new outreach and education strategy to improve dementia care for rural older adults and develop new dementia care training and resources for Hispanic and Latino care providers and patient families.

Aim 1 is to conduct an intervention study in 10 rural Iowa counties with large percentages of older residents, and compare prescribing patterns and patient outcomes in these 10 counties compared to 20 counties with similar resident characteristics. Our intervention will include:

1. Local extension office outreach to deliver our toolkit and marketing materials and to recruit prescribers, consultant pharmacists, and nursing home directors of nursing and administrators for academic detailing (ie, educational discussions with academic specialists

2. Four academic detailing sessions over six months with a psychiatric pharmacy specialist or nurse specialist in geriatric psychiatry, using videoconferencing equipment to improve the sustainability of the approach for rural settings

3. Multidisciplinary team consultation for challenging clinical scenarios, the results of which will be delivered as guidance to academic detailing participants and form the foundation for future resources.

Aim 2 is to translate our existing online training program and toolkit to into Spanish and distribute this translation. Aim 3 is to evaluate long-term outcomes associated with use of our online training program

and toolkit in Iowa. Antipsychotic use patterns and behavioral outcomes for Aims 1 and 3 will be evaluated by analyzing Minimum Data Set, Medicare, and Medicaid data for Iowa beneficiaries from 2009 to 2014.

Maryland

Claire Snyder, PhD
JOHNS HOPKINS UNIVERSITY
Presenting Patient-Reported Outcomes Data to Improve Patient and Clinician Understanding and Use

Background: Patient-reported outcomes (PROs), such as symptoms and quality of life, assess the impact of a health condition and its treatment from the patient perspective and are commonly included in research studies. PROs can also be used to help manage an individual patient's care. However, there are many different questionnaires that have been developed to measure PROs, and there is no standard way to score and present PRO results. Higher scores may represent better or worse outcomes depending on the measure or depending on the domain within a measure. This variation makes it difficult for patients and clinicians to understand and use the PRO results. Given PROs' potential to help clinicians and patients tailor care to a particular patient's needs, there is a critical need for research on how to present PRO data so that the results are meaningful and useful for patients and clinicians.

OBJECTIVE: The study aims to:

1. Learn how current ways of presenting PRO results limit patient and clinician understanding

2. Develop new approaches for presenting PRO results to improve patients' and clinicians' ability to use the findings

3. Evaluate how well the new approaches work in improving patient and clinician understanding and use of PRO data. The long-term objective is to develop best practices for presenting PRO data to patients and clinicians, thereby improving the ability of patients and clinicians to make treatment decisions to meet a particular patient's needs.

Methods: We propose a three-year, three-part study to test different ways of scoring and presenting PRO data. The research will be conducted through the Johns Hopkins Clinical Research Network (a collaboration of teaching hospitals and community practices), supplemented with an Internet survey of key stakeholder groups. The study will include patients who have different amounts of education to make sure the results make sense to patients across education levels. Because cancer has been a major PRO research focus, this study will be conducted in cancer patients and clinicians, though we expect the results to apply across different kinds of diseases. In Part 1, we will interview 70 clinicians and 200 patients to (a) see how well they understand PRO data presented using existing approaches and (b) find out what they did and did not like about the existing approaches. In Part 2, we will use the Part 1 results and work with stakeholders to develop new approaches for presenting PRO data to promote understanding and use. Part 3 will be an evaluation of the approaches developed in Part 2 in more than 1,000 patients and more than 250 clinicians, both within the Johns Hopkins Network and through an

Internet survey of stakeholder groups. To help us understand these evaluations better, we will also interview a subset of the subjects from Part 3. A stakeholder advisory board of patients/caregivers, clinicians, and PRO developers/researchers will inform study design, conduct, and put the results into practice.

Massachusetts

Jennifer W. Mack, MD, MPH
DANA-FARBER CANCER INSTITUTE
Relapsed Childhood Neuroblastoma as a Model for Parental End-of-Life Decision Making

Parental end-of-life (EOL) decision making for children with cancer is often poorly informed. Many parents have overly optimistic beliefs about prognosis and, as a result, choose aggressive measures at the EOL, which are associated with greater suffering. Yet most parents wish to limit suffering, and, in retrospect, many regret choices for EOL cancer treatment. These findings suggest that many parents are not sufficiently informed to make decisions that reflect their preferences.

The proposed study will evaluate parental EOL decision making, addressing gaps in the literature in three important respects:

1. Previous work on EOL decision making for children with cancer has typically looked at decisions at one point in time, often asking parents to reflect on decisions after the child's death, even though parents' understanding of prognosis and decisions about care evolve over time. We will evaluate parental EOL decision making over time.

2. Existing work focuses on aggressive EOL care as the worst possible outcome. However, some parents wish to pursue aggressive measures even when they recognize that the child has no realistic chance for cure. We will evaluate the extent to which parental decision making is informed and consonant with preferences, regardless of whether decisions lead to aggressive or palliative care.

3. Previous studies have focused on groups of different childhood cancers, making it difficult to ascertain whether differences in decision making reflect differences in diseases, options for care, or parent preferences. We will focus on a single disease, relapsed neuroblastoma, as a model for EOL decision making. Children with relapsed neuroblastoma have incurable cancer but many options for care, including established cancer regimens, clinical trials, and palliation. Relapsed neuroblastoma presents an ideal model for parental decision making in the setting of a complex array of choices for children nearing the EOL.

We will follow 120 parents at eight institutions over time, beginning at relapse and continuing over 18 months. Parent interviews every three months and reviews of medical records throughout that time will be used to evaluate the ways that parental preferences for the aggressiveness of treatment change over time (Aim 1). Parental perception that care has been burdensome will be evaluated as a possible driver of change in EOL decision making (Aim 2). Ideally, parent values for care would be the primary driver of treatment goals. Thus, we will evaluate the extent to which parental understanding of prognosis,

treatment options, and expected benefits and burdens of treatment can allow decision making consonant with parental preferences in the absence of prior negative experiences with care (Aim 3). Finally, in-depth parent interviews will allow us to evaluate personal factors that drive parental EOL decision making (Aim 4). Throughout the study, a parent advisory group will guide assessment of EOL care preferences and decision making.

Michigan

David E. Sandberg, PhD
UNIVERSITY OF MICHIGAN AT ANN ARBOR
Decision Support for Parents Receiving Genetic Information About Child's Rare Disease

The birth of a child with a disorder of sex development (DSD) is stressful for parents and members of the healthcare team. The "right" decisions about gender assignment (Is it a boy? A girl?) and the best course of action (Should there be surgery? What kind? When?) are not obvious. While there have been large advances in diagnostic assessments such as genetic testing, the tests do not always show what caused the DSD. And, even when the tests do show a genetic explanation for the DSD, knowing what happened genetically does not usually lead to a single "correct" treatment plan. Instead, it is likely that there are several good treatment options—and parents will need to made decisions based, in part, on their personal preferences, values, and cultural background. Adding more stress to the situation is knowledge that many of the decisions that need to be made by parents early in a child's life are irreversible and exert life-long consequences for the child and the family.

To support parents becoming actively involved in making those decisions, and to reduce the likelihood of future worry and regret about decisions that have been made, we will create a decision aid (DA). The DA will help educate families about typical and atypical sex development of the body; the process by which DSDs are diagnosed (especially how to interpret genetic test results); and possible relationships between diagnostic/genetic testing, decisions about care, and known consequences of those decisions on their child and entire family. The DA will be used by parents of young children together with their child's healthcare provider.

We will bring together a network of researchers, healthcare providers, representatives of patient support and advocacy organizations, and parents of children with DSD to share their experiences. Participants of this network will be involved at each stage of creating the DA, revising it, and putting it into practice. At the end of this project, we will have a fully formed and tested DA that will be available for parents to use with their child's healthcare team as they are first learning their child may have a DSD.

Ohio

Kurt C. Stange, MD, PhD
CASE WESTERN RESERVE UNIVERSITY
Patient-Identified Personal Strengths (PIPS) vs Deficit-Focused Models of Care

Most current approaches to patient care are focused on patients' symptoms, limitations, and weaknesses. This approach can guide medical treatment, but it does not unleash the transformative power of people's positive personal strengths that can help patients to live a fulfilling life despite having multiple chronic illnesses. A growing body of research points to the potential of bringing patient-identified personal strengths (PIPS) into illness management to achieve better patient-centered outcomes.

Our team has conducted groundbreaking work in developing and evaluating symptom-focused computer-supported Interactive Tailored Patient Assessment Tools (ITPAT) and in engaging patients and clinician stakeholders in participatory group model building to compare the effectiveness of different therapeutic approaches. In addition, we have developed a highly participatory practice-based research network (PBRN) of safety net practices serving disadvantaged patient populations.

We propose that focusing care on patient strengths can result in enhanced health behaviors and better patient-centered outcomes by motivating positive change and engaging patients in ways that the usual deficit-based model of care cannot. Therefore, we aim to:

1. Identify patient-identified personal strengths relevant to chronic illness management.

2. Develop a strength-focused computer-supported Interactive Tailored Patient Assessment Tool.

3. Engage patients, caregivers, and primary care clinicians in identifying mechanisms by which leveraging PIPS in different ways might affect processes and patient-centered outcomes of care.

4. Use computer models to simulate the effect of alternate approaches to leveraging PIPS in practice on patient-oriented outcomes and provider resources compared to usual deficit/illness-focused care.

These aims will be accomplished through a collaboration between patients with multiple chronic conditions, poverty, and racial and ethnic minorities; caregivers, clinicians, and researchers from different fields. Together, we will:

• Engage patients and caregivers from the PBRN network in Appreciative Inquiry focus groups to identify PIPS.

• Work interactively with these focus groups to use the identified PIPS to develop a computer-supported ITPAT.

• Use the Patient Strengths ITPAT in qualitative system dynamics group model building sessions to identify mechanisms by which assessments of patient strengths in primary care encounters can affect the processes and outcomes of care.

• Use the identified mechanisms to build simulation models that compare usual deficit/illness-focused care to care that is informed by patient-identified personal strengths.

This research will generate a useful new tool, simulation models, and knowledge that can be used to make health care more effective in producing patient-centered outcomes.

Addressing Disparities

Alabama

Beverly E. Thorn, PhD
UNIVERSITY OF ALABAMA IN TUSCALOOSA
Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial

Chronic pain is a significant public health problem that affects more than 116 million Americans; costs $600 billion annually; and is unequally borne by people in low-income brackets, especially ethnic minorities. Many individuals also have health literacy deficits (difficulty understanding their illness and difficulty navigating the healthcare system for treatment), putting them at a greater disadvantage in the healthcare system. Treatment usually relies on expensive medical interventions with negative side effects. Psychosocial treatments, such as Pain Education and Cognitive-Behavioral Therapy (CBT), show promise, but are usually unavailable. Clinicians are poorly equipped to provide psychosocial treatments to patients with low health literacy. Cognitive-behavioral therapies have not been adapted and supported for use in individuals with low health literacy, and even educational materials are often poorly adapted for their needs.

To address this problem, the applicant recently completed a small trial showing initial effectiveness of health literacy–adapted pain education and CBT groups for chronic pain in a population with low income and low health literacy. Patients in both treatments reported lower pain by the end of treatment, and the effects were maintained at one year. Patients in the CBT group also reported fewer symptoms of depression after treatment. The current study uses a larger number of participants and directly compares these psychosocial treatments to medical treatment as usual, with the goal of supporting their widespread use in community settings. Our research questions are:

1. In people with chronic pain and low income and/or low education, does participating in a health literacy–adapted psychosocial treatment group improve their pain, and interference in daily activities due to pain, by the end of treatment when compared with a group receiving typical medical care, and are these effects maintained six months later?

2. Does participation in the CBT pain management group improve symptoms of depression better than a pain education group by the end of treatment, and are these effects maintained six months later?

Building on an ongoing partnership with a federally qualified health consortium that serves the highly disadvantaged Black Belt region of West Alabama, we will enroll 294 patients with chronic pain. The

most important outcomes will be patient-reported pain intensity, interference in daily activities due to pain, depression, and self-reported impressions of overall improvement after treatment. We will use accepted statistical analyses to examine our findings. Based on our earlier study, we expect that our participants will be ~75% female, ~70% African American, and financially disadvantaged, with 60% scoring in the bottom 15% nationally on word reading and 90% at or below the poverty threshold.

California

Kenneth Brooks Wells, MD, MPH
UNIVERSITY OF CALIFORNIA LOS ANGELES
Long-term Outcomes of Community Engagement to Address Depression Outcomes Disparities

This study extends an existing study in Los Angeles that is partnered between academic and community and client stakeholders. The study has the long-term goal of learning collaboratively how to eliminate disparities in outcomes for persons with depression by improving information and services in inner-city communities of color, using two Los Angeles communities as examples. Much is known about how to treat depression, but there are gaps in access, quality, and outcomes of care that raise the burden of illness from depression in minority communities—and little is known about how to address these gaps. This study builds on an existing project, Community Partners in Care, in which different kinds of community-based agencies were assigned at random to having technical assistance as an individual agency to use toolkits to improve depression services and outcomes, or to work together across agencies to tailor the use of the toolkits to the strengths of the community and to collaborate as a network to improve depression outcomes. That study is just finishing and final results show that, at six-month follow-up, the community engagement and network activation approach, compared to technical assistance, improved clients' mental health and physical functioning and reduced risk factors for homelessness. These findings suggest that clients might benefit over a longer period of time. In addition, to build stronger collaborative systems for the future, it would be important to know how clients prioritize among such diverse outcomes and how providers and clients would work better together to address clients' priorities.

The proposed study asks for funding to support data collection to compare three-year outcomes of clients under the two conditions, community engagement and technical assistance, particularly in their health outcomes, risk for homelessness, and employment outcomes, which are high priorities of clients and community stakeholders. The interventions could affect long-term outcomes directly or indirectly through earlier effects on health and social factors. We will study both pathways. We also propose to collect and analyze rich narrative information to understand what outcomes are important to depressed clients and how they make decisions about getting help to address them. Similarly, we want to collect data to understand whether and how providers address depressed clients' priorities for outcomes and services and to host community discussions across stakeholders on how to design programs through collaboration to better address clients' priorities. The research effort is "partnered" or done collaboratively with community members and clients.

Colorado

Amanda Frisch Dempsey, MD, PhD, MPH
UNIVERSITY OF COLORADO DENVER
Cultural Tailoring of Educational Materials to Minimize Disparities in HPV Vaccination

Background: Human papillomavirus (HPV) infection is the most common sexually transmitted infection worldwide, affecting more than 80% of women by age 50 in the United States. More than six million women are infected annually with HPV, resulting in one million new cases of genital warts; three to five million abnormal Pap smears; and 12,000 cases of cervical cancer each year. Although infection afflicts all levels of society, health consequences and death related to HPV is much higher among racial and ethnic minorities than other groups. When an effective HPV vaccine was licensed in 2006, many hoped that it would help to eliminate these disparities in HPV-related diseases. Instead, studies have shown that the populations at highest risk for HPV-related health consequences also have the lowest levels of HPV vaccination. There is a great need to find interventions to improve HPV vaccination among these high-risk populations.

Objectives: The focus of this proposal is to increase HPV vaccination rates among Latinas, who have the highest risk for developing invasive cervical cancer, compared to all other racial/ethnic groups. The long-term objective of this research is to compare three different approaches to helping Latinas make decisions about the HPV vaccine. The aims of the study are to:

1. Revise an existing decision-support tool about HPV vaccines to create “VaxFacts-Latina,” an individually and culturally tailored tool for HPV vaccine decision making among Latinas.

2. Compare VaxFacts-Latina to an untailored version of the tool and to “usual care” to determine if these three approaches to informing people about the vaccine result in differences in how people feel about making the vaccination decision (ie, the “quality” of the HPV vaccination decision).

3. Compare the impact of these three approaches on Latina HPV vaccination rates.

Methods: This project will consist of two distinct phases. In Phase I, focus groups and feedback from a Community Advisory Board (CAB) comprised of parents of Latina adolescents and young adult Latinas will be used to create VaxFacts-Latina. In Phase II, a three-armed randomized controlled trial will compare VaxFacts-Latina to an untailored version of the tool and to “usual care” (a two-page generic written handout about the vaccine). Measures reflecting the “quality” of the decision-making process for HPV vaccination and HPV vaccination rates among Latinas will be compared between the three arms. The estimated sample size for the trial is 951 people (317/arm). The CAB will be involved in all phases of the project, including designing the specific research questions to be addressed by the intervention comparisons, developing the interventions, planning the interventions’ implementation, and disseminating results of the study to the broader Hispanic community.

Kentucky

Debra Kay Moser, DNSc, RN
UNIVERSITY OF KENTUCKY
Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors

Appalachian Kentucky is in the top 1% of the nation in cardiovascular disease (CVD) morbidity and mortality. Individuals in Appalachian Kentucky are vulnerable to CVD because they have high rates of multiple CVD risk factors. This problem is amplified by the poverty striken environment. There is a critical need to test sustainable CVD risk-reducing interventions appropriate for Appalachia. In the absence of such interventions, the dramatic CVD disparities seen in this area will continue.

Lifestyle intervention can reduce CVD risk by 44%. We have demonstrated that lifestyle change is most effective when patients are given the tools to engage in self-care and that patient-centered interventions individualized to patients' needs and barriers are more effective than interventions that are not. We believe, based on research evidence, that to be successful in poor environments where access to health care is limited, CVD risk-reducing interventions must focus on patient-centered lifestyle change that increases individuals' abilities to engage in self-care, be culturally appropriate, and have components that overcome barriers in such environments.

We propose to compare the effects of two approaches to CVD risk reduction in 300 individuals from Appalachian Kentucky who do not have a primary care provider (and thus are not able to receive the standard of care without intercession) and who are at risk for CVD by virtue of having two or more modifiable CVD risk factors. We will compare (a) the standard of care alone and referral to a primary care provider for management of CVD risk factors with (b) standard of care supplemented by patient-centered, culturally appropriate, self-care CVD risk reduction intervention (HeartHealth) designed to improve multiple CVD risk factors while overcoming barriers to success. We hypothesize that the HeartHealth intervention, with an emphasis on self-care, will produce superior outcomes, compared to standard of care, which has met with limited success in producing sustained CVD risk reduction.

We propose to compare the 4-month (short-term) and 1-year (long-term) impact of the interventions on:

1. The CVD risk factor selected by patients (ie, tobacco use, blood pressure, lipid profile, HgA1c for diabetics, body mass index, waist circumference, depressive symptoms, or physical activity level)

2. All of the CVD risk factors of each patient

3. Quality of life

4. Patient and healthcare provider satisfaction

5. Desirability and adoptability by assessing adherence to recommended CVD risk reduction measures and retention of recruited individuals

This study will have a substantial impact on cardiovascular health because it will provide needed patient-centered CVD risk reduction to a major at-risk population living in an environment where CVD risk reduction is difficult. The potential for application to other environments and high-risk populations is high.

Table 1: PCORI PFA Cycle I Awardees: Project Period and Award Amount

Priority Area	Principle Investigator	Project Title	Contract Period (Years)	Requested Reward Amount
Assessment of Prevention, Diagnosis, and Treatment Options	Schneider	A Comparison of Non-Surgical Treatment Methods for Patients with Lumbar Spinal Stenosis.	3	$ 1,678,663.00
Assessment of Prevention, Diagnosis, and Treatment Options	Loring	Cognitive AED Outcomes in Pediatric Localization Related Epilepsy (COPE)	3	$ 2,057,028.20
Assessment of Prevention, Diagnosis, and Treatment Options	Leslie	Comparative effectiveness of adolescent lipid screening and treatment strategies	2	$ 989,288.80
Assessment of Prevention, Diagnosis, and Treatment Options	Keren	Comparative Effectiveness of Intravenous v. Oral Antibiotic Therapy for Serious Bacterial Infections	3	$ 1,930,855.00
Assessment of Prevention, Diagnosis, and Treatment Options	Prvu Bettger	Comparative Effectiveness of Rehabilitation Services for Survivors of an Acute Ischemic Stroke	3	$ 894,620.00
Assessment of Prevention, Diagnosis, and Treatment Options	Cherkin	Evaluation of a Patient-Centered Risk Stratification Method for Improving Primary Care for Back Pain	3	$ 1,881,433.60
Assessment of Prevention, Diagnosis, and Treatment Options	Cox	Improving Psychological Distress Among Critical Illness Survivors and Their Informal Caregivers	3	$ 1,850,897.60
Assessment of Prevention, Diagnosis, and Treatment Options	Tentori	Selection of Peritoneal Dialysis or Hemodialysis for Kidney Failure: Gaining Meaningful Information for Patients and Caregivers	3	$ 1,884,398.40
Assessment of Prevention, Diagnosis, and Treatment Options	Hess	Shared Decision Making in the Emergency Department: The Chest Pain Choice Trial	3	$ 2,039,974.00

Priority Area	Principle Investigator	Project Title	Contract Period (Years)	Requested Reward Amount
Improving Healthcare Systems	Hsu	Creating a Clinic-Community Liaison Role in Primary Care: Engaging Patients and Community in Health Care Innovation	3	$ 1,557,898.00
Improving Healthcare Systems	Temkin-Greener	Improving Palliative and End-of-Life Care in Nursing Homes	3	$ 1,468,738.00
Improving Healthcare Systems	DeVoe	Innovative Methods for Parents And Clinics to Create Tools (IMPACCT) for Kids' Care	3	$ 1,737,233.00
Improving Healthcare Systems	Schuster	Optimizing Behavioral Health Homes by Focusing on Outcomes that Matter Most for Adults with Serious Mental Illness	3	$ 1,726,710.00
Improving Healthcare Systems	Schnipper	Relative Patient Benefits of a Hospital-PCMH Collaboration within an ACO to Improve Care Transitions	3	$ 1,904,823.00
Improving Healthcare Systems	Reeves	The Family VOICE Study (Value Of Information, Community Support, and Experience): a randomized trial of family navigator services versus usual care for young children treated with antipsychotic medication	3	$ 1,412,083.76
Communication and Dissemination Research	Sandberg	Decision Support for Parents Receiving Genetic Information about Child's Rare Disease	3	$ 1,373,164.00
Communication and Dissemination Research	Carnahan	Extension Connection: Advancing Dementia Care for Rural and Hispanic Populations	3	$ 1,610,580.00
Communication and Dissemination Research	Stange	Patient-Identified Personal Strengths (PIPS) vs. Deficit-Focused Models of Care	3	$ 1,739,717.60
Communication and Dissemination Research	Snyder	Presenting Patient-Reported Outcomes Data to Improve Patient and Clinician Understanding and Use	3	$ 697,104.34
Communication and Dissemination Research	Mack	Relapsed childhood neuroblastoma as a model for parental end-of-life decision-making	3	$ 985,992.00
Communication and Dissemination Research	Wysocki	Shared Medical Decision Making in Pediatric Diabetes	3	$ 2,080,367.60

Priority Area	Principle Investigator	Project Title	Contract Period (Years)	Requested Reward Amount
Addressing Disparities	Dempsey	Cultural tailoring of educational materials to minimize disparities in HPV vaccination	3	$ 1,548,804.00
Addressing Disparities	Wells	Long-term outcomes of community engagement to address depression outcomes disparities	3	$ 2,064,163.00
Addressing Disparities	Thorn	Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial	3	$ 1,279,112.00
Addressing Disparities	Moser	Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors	3	$ 2,092,473.00